



916-342-4133
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510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Pin, fixation, smooth.
Common/usual name: Fixation wire, fixation pin, and others
Proprietary name: Block Stop Wires
- B. Substantial equivalence: Kirschner Medical Wire and Steinman Pins (K831005), and others.
- C. Device description: The Block Stop Wires device is an internal wire fixation device to be used on various types of articular fractures.
- D. Intended use: The Block Stop Wires device is intended for use in the osteosyntheses of epiphyseal fractures with small osteo-articular fragments and for temporary support of dislocations of small articulations.
- E. Technological characteristics: The Block Stop Wires device is similar to predicate devices in its design, function, and intended use.